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(54) A dosing device for adding an additive gas or liquid to breathing gas in an anaesthesia machine or ventilator

(57) A dosing device for adding small amounts of an additive gas or liquid, such as NO or liquid anaesthetic, to a breathing gas in an inspiratory line in an anaesthetic machine or ventilator, comprises a constant-volume dosing chamber (6). The dosing chamber has an inlet (2), equipped with a first valve (4), for connection to a source of gas or liquid supplying the additive gas or liquid at a predetermined, constant, positive pressure, and an outlet (10), equipped with a second valve (8), for

injecting gas or liquid from the dosing chamber into breathing gas. Control means (20, 22) are arranged to open and close the valves (4, 8) in a controlled fashion. A control unit is also arranged to cause the operating means (20, 22) to open the second valve (8) for one or a plurality of predetermined intervals during the inspiratory phase.

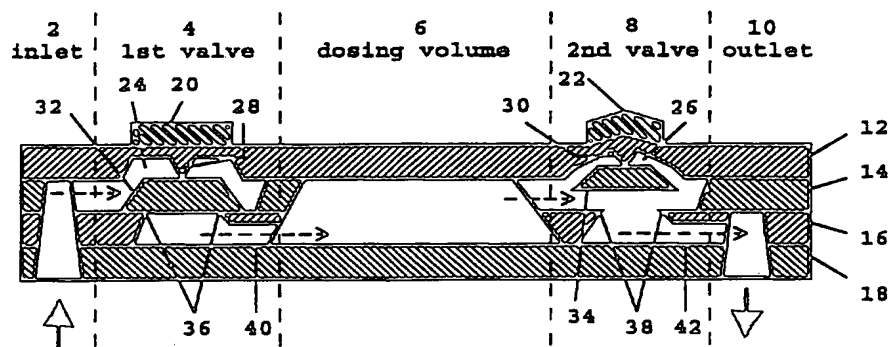


FIG. 1

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## Description

The present invention relates to a dosing device for adding small amounts of an additive gas or liquid to a breathing gas, intended to be supplied to a subject via an inspiratory line in an anaesthetic machine or ventilator during inspiratory phases.

In this application the phrase "additive gas" refers to any mixture of gases, diluted or undiluted, as well as pure gases. For instance, NO diluted in N<sub>2</sub> can be used as additive gas, pure xenon can be used as additive gas, liquid anaesthetic can be used as additive liquid, vaporised anaesthetic (pure or diluted) can be used as additive gas.

In inhalation anaesthetic, small amounts of anaesthetic is added to breathing gas for inhalation by a subject. The anaesthetic can be supplied to the breathing gas in the form of gas or liquid. When supplied in form of gas, some of the breathing gas is allowed to bubble through or pass across the surface of a liquid anaesthetic in order to vaporise same. The resulting mixture, containing a relatively high concentration of anaesthetic, is then added to the rest of the breathing gas in a controlled fashion. The anaesthetic can also be delivered directly into the breathing gas as a liquid, whereupon it quickly vaporises. In the latter case, some kind of heating may be necessary in order to avoid cold gas from reaching the subject and to enhance the vaporisation of the liquid.

Other substances that can be supplied, preferably near the subject, are NO, surfactant and other therapeutic substances.

The Swedish patent SE - C - 448 347 describes a method for mixing gases in predetermined proportions and dosing the gas mixture in conjunction with anaesthesia and respirator care. Different gases are pulse-injected into a mixing chamber for mixing in same and subsequent dosing of the gas mixture. The proportions of the different gases are governed by the volumes of the gas pulses.

Accurate dosing of small amounts of gas or liquid in a safe manner is difficult and problematic. Known dosing devices normally operates with relatively large volumes of the additive, from which dosing volume the additive gas/liquid is taken. If a fault occurs in the device, relatively high doses can be taken from the dosing volume. Even if other security measures for the patient interfere, the patient may still be exposed to quantities that could cause discomfort, and in the worst case even be harmful or lethal.

The object of the present invention is to achieve a new type of dosing device, for gases and/or liquids, making possible the reliable and exact addition of (in particular) small doses of specific additive gases or a liquid, such as anaesthetic liquid, to a main flow of breathing gas supplied to the subject. The doses to be supplied are small, up to the order of 500 ml/min.

This object is achieved in accordance with the invention in that the dosing device is devised as set forth

in the characterizing portion to claim 1.

Great safety and reliability with exact dosing are achieved with the dosing device according to the invention. The dosing device is small and can therefore be located close to the subject. Hereby any dead space preventing the dose from reaching the subject in the desired manner is avoided. The dosing device comprises a first valve at an inlet, connected to an intermediate dosing chamber, and a second valve at an outlet. The dosing chamber has a volume essentially in the magnitude of the dose to be supplied during one inspiratory phase. Even if the entire dosing volume for some reason should be emptied into the breathing gas, any overdose would be kept low and may not even cause discomfort for the patient. The use of two valves increases safety, especially when they are controlled so that only one valve at a time is open for passing additive gas or liquid.

Dosing can be controlled by controlling the number and duration of the second valve's opening times during inspiration a controlled amount of additive gas or liquid is supplied to the breathing gas from the dosing chamber. By using a dosing chamber slightly larger than the dosage to be delivered during the inspiratory phase, the output pulses of additive gas or liquid will be dispensed at an essentially constant pressure, thereby contributing to exact dosing. For safety reasons, both valves are advantageously kept closed when no gas or liquid is to be passed into the dosing chamber or to the breathing gas.

According to one advantageous embodiment of the dosing device in accordance with the invention, a control unit is arranged to cause operating means to open the first valve first, so as to fill the dosing chamber with gas or liquid under positive pressure, thereafter closing the first valve and opening the second valve. Thus, the dosing chamber fills when the first valve opens while the second valve is closed, whereupon the first valve is closed and the second valve is opened for brief, controlled periods of time to inject the desired dosing volume into the main flow. So there is never any direct connection between the source of gas or liquid and the patient. The opening of the first valve can be made during the expiratory phases.

This provides for an alternate control to achieve the accurate dosing. By alternately opening and closing the valves during the inspiratory phase. The dosing chamber can be refilled one or several times during the inspiratory phase.

This can also be used when larger doses of the additive gas or liquid is to be supplied. The first and second valves can then alternately be opened and closed during the inspiratory phase. Hereby, the dosing chamber will contain an exact volume at an exact pressure each time the second valve opens during the inspiratory phase and dosing becomes more accurate. In this case, the dosing chamber can be made much smaller than the total dose to be given.

It is also possible to allow both valves to be open

simultaneously, in particular if the additive gas or liquid is in no way discomforting or harmful to the patient. Alternately, other precautions for avoiding overdosing can be used, such as a diffusion membrane between the dosing device and the breathing gas. The diffusion of gas/liquid through the membrane will then govern the maximum dose that can be supplied to the patient.

Yet another way of accomplishing the dosing is to open the second valve during the dosing period of the inspiratory phase and then control the dosing by opening and closing the first valve. In such case, the dosing chamber can be considerably smaller than the dose to be supplied.

According to another advantageous embodiment of the dosing device in accordance with the invention, the operating means consist of piezoelectric elements which, when activated, are devised to lift a valve body off its valve seat in order to open the valve. This results in a valve which respond rapidly to activation, compared to the response of bimetallic actuators (laminates with different coefficients of linear, thermal expansion) employed as operating means. In this embodiment, the valve body is also lifted by piezoelectric actuators exerting great force, compared to the force generated when electrostatic actuators are employed as operating means. This embodiment of the dosing device according to the invention ensures that the dosing device's valves operate rapidly and reliably and have a simple design.

According to an additional advantageous embodiment of the dosing device in accordance with the invention, the dosing device is devised so the positive pressure of a connected source of gas or liquid acts to close the valve body. The closing and sealing effect of the positive pressure, typically 5 bars, of the source of gas or liquid is a major advantage from the safety point of view.

According to yet another advantageous embodiment of the dosing device in accordance with the invention, the apparatus is made by micromachining silicon. Micromachining silicon (using microelectronic technology) makes it possible to manufacture small, identical dosing devices with high performance distribution of gas or liquid at low cost. This fabrication technology therefore makes mass-manufacturing possible at low cost. So the dosing device could conceivably be devised as a disposable article.

The invention will now be explained in greater detail by describing two exemplifying embodiments of the dosing device according to the invention and referring to the drawings in which

FIG. 1 shows a cross-section of a first embodiment of the dosing device according to the invention,  
 FIG. 2 shows a schematic depiction of a second embodiment of the dosing device according to the invention,  
 FIG. 3 shows a first set of diagrams illustrating a first possible mode of operating the embodiment in

FIG. 2,

FIG. 4 shows a second set of diagrams illustrating a second possible mode of operating the embodiment in FIG. 2,

FIG. 5 shows a third set of diagrams illustrating a third possible mode of operating the embodiment in FIG. 1, and

FIG. 6 shows the dosing device connected to a ventilator/anaesthetic machine.

FIG. 1 shows a cross-section of a first embodiment of the dosing device according to the invention. The dosing device consists of an inlet 2, a first valve 4, a dosing chamber (dosing volume) 6, a second valve 8 and an outlet 10 laterally arranged on micromachined discs 12, 14, 16, 18 and possibly glass to which the discs 12, 14, 16, 18 have been bonded.

One piezoelectric element 20, 22 is glued in each of the valve areas 4, 8 on top of the disc 12. These valve areas 4, 8 have notches 24, 26 in the disc 12 and a central pin 28, 30 to which a valve body 32, 34 is attached. The valve bodies 32, 34 are set on respective valve seats 36, 38, arranged in the disc 16.

When a piezoelectric element 22 is activated, it causes the disc 12 to bulge upwards in its valve area, as illustrated in FIG. 1 for the second valve 8. Here, the valve body 34, attached to the central pin 30, is lifted off the associated valve seat 38. The dosing chamber 6 is then coupled to the dosing device's outlet 10 via the channel 42.

The first valve 4 is devised in the same way as the second valve 8 and is shown closed in FIG. 1 with the valve body 32 pressing against its valve seat 36 as the piezoelectric element 20 is not activated. A channel 40 leads additive gas or liquid to the dosing chamber 6 when the first valve 4 is open.

The path of the additive gas or liquid through the dosing device is designated with dashed arrows. The gas/liquid enters the dosing device at the inlet 2, passes through the first valve 4 to the dosing chamber 6 and from the dosing chamber 6, through the second valve 8 to the outlet 10.

Since piezoelectric elements 20, 22 are used as operating means for the valves 4, 8, the valves 4, 8 can be operated rapidly, and the valve bodies 32, 34 are lifted with relatively great force, also resulting in rapid and reliable valve operation. The response time of the valves is in the order of 1 ms.

For safety reasons, both valves 4, 8 are normally closed and only open when voltage is applied to the piezoelectric elements 20, 22. The valve bodies 32, 34 are also designed so feed pressure exerts a closing and sealing effect on the valves 4, 8. Since feed pressure is relatively high, as noted above, the valves 4, 8 should appropriately be pressure-balancing, i.e. counter-balance the high feed pressure, enabling closed valves to be opened by relatively light force.

The dosing device can be operated as follows:

The first valve 4 is opened by activation of the pie-

zoelectric element 20, and the dosing chamber 6 fills with an additive gas or liquid, such as NO or liquid anaesthetic, from a source of gas or liquid at a constant positive pressure, typically 5 bars, connected to the inlet 2. The first valve 4 is then closed, and the second valve 8 is opened for a number of brief, controlled periods of time by corresponding activation of the piezoelectric element 22, so the desired dose of additive gas or liquid is expelled from the dosing chamber 6 and into the outlet 10 which is directly connected to the main flow of breathing gas. The duration and number of pulses determine the total dose.

Allowing only one of the valves 4, 8 at a time to be opened increases safety for patient, since there is never a direct connection between the gas/liquid source and the patient. Depending on inter alia which substance that is added and the amount of substance to be added, the valves 4, 8 may at some instances be operated to be simultaneously open for allowing a greater flow of gas/liquid.

Control of the valves 4, 8 also depends on the selection of size of the dosage chamber 6. Alternate operations for the first embodiment is discussed in more detail in relation to figs. 3-5.

FIG. 2 shows another embodiment of the dosing device according to the invention. In this embodiment, the first valve 54, the dosing chamber 56 and the second valve 58 are arranged in a stack and correspondingly fabricated in a silicon housing 59. This embodiment also includes piezoelectric elements 70 and 72 for operating the valves 54, 58.

The dosing device's outlet is directly connected to a line 61 carrying the main flow of breathing gas.

A diffusion membrane 63 is in this case arranged as an extra safety precaution at the dosing device's outlet. The purpose of this membrane 63 is to prevent excessively high doses of additive gas or liquid from being injected into the breathing gas if both the valves 54, 58 end up in the open position due to a malfunction. Such extra precaution can be used when therapeutically active substances that are harmful in relatively small doses or substances that may become lethal after chemical reactions are being dosed. One such substance is NO. Several investigations indicate very positive therapeutic effects of NO when given to patients in extremely small doses (less than ca 100 ppm). Yet, NO is a harmful gas above a certain concentration, and can even become lethal when it reacts with oxygen and forms NO<sub>2</sub>.

The embodiment in FIG. 2 indicates that the dosing device in this case is connected to a source of NO.

Upstream from the inlet valve 54, there is a space 55 which is directly connected to the source of additive gas, NO in this embodiment. This space 55 accordingly holds additive gas at the prevailing positive pressure. Space 55 can be viewed as an inlet to the dosing device.

FIG. 3 shows by way of three diagrams an example of one way of operating the dosing device for dosing the

additive gas or liquid. In this case reference is made to the second embodiment in FIG. 2, but the same operation can be applied on the dosing device according to the first embodiment in FIG. 1.

Diagram A shows the chronological sequence for activation of the piezoelectric element 70 for the first valve 54, diagram B shows the chronological sequence for activation of the piezoelectric element 72 for the second valve 58 and diagram C shows a respiratory cycle consisting of an inspiratory phase and an expiratory phase.

As this example shows, voltage is applied to the piezoelectric element 70 throughout the inspiratory phase, the first valve 54 being therefore open the whole inspiration time. Three brief voltage pulses are applied to the second valve's 58 piezoelectric element 72 during the initial part of the inspiratory phase, and three corresponding pulses of additive gas are accordingly injected into the main flow of breathing gas.

In the dosing operation described above, both the inlet valve 54 and the outlet valve 58 are open during the said brief pulses. The dosage chamber 56 can therefore be smaller than the dose to be supplied during the inspiratory phase. In fact, the dosing chamber 56 can be much smaller than the dose to be supplied.

As noted above, closing the inlet valve before the outlet valve opens may be preferable from the safety point of view. This operating procedure is obviously even possible with the embodiment in FIG. 2. However, as an additional safety feature to prevent excessively high doses of additive gas, a diffusion membrane 63 can be arranged in the outlet as noted in the embodiment in FIG. 2 above.

FIG. 4 shows by way of three diagrams a second way of operating the dosing device for dosing. In this case also, reference is made to the second embodiment in FIG. 2, but the same operation can be applied for the dosing device according to the first embodiment in FIG. 1.

Diagram D shows the chronological sequence for activation of the piezoelectric element 70 for the first valve 54, diagram E shows the chronological sequence for activation of the piezoelectric element 72 for the second valve 58 and diagram F shows a respiratory cycle consisting of an inspiratory phase and an expiratory phase.

As this second example shows, voltage is applied to the piezoelectric element 70 at intervals during the inspiratory phase, the first valve 54 being therefore open at these times only for filling the dosing chamber with additive gas. Three voltage pulses are applied to the second valve's 58 piezoelectric element 72 in-between these openings of the first valve 54, and three corresponding pulses of additive gas are accordingly injected into the main flow of breathing gas.

In this case safety is maximal, since there is no time when gas can flow directly from the source to the flow of breathing gas. The dosing chamber 56 can in this case also have a (considerably) smaller volume than the

dose to be supplied.

FIG. 5 shows by way of three diagrams a third way of operating the dosing device for dosing. In this case also, reference is made to the second embodiment in FIG. 2, but the same operation can be applied for the dosing device according to the first embodiment in FIG. 1.

Diagram G shows the chronological sequence for activation of the piezoelectric element 70 for the first valve 54, diagram H shows the chronological sequence for activation of the piezoelectric element 72 for the second valve 58 and diagram I shows a respiratory cycle consisting of an inspiratory phase and an expiratory phase.

As this third example shows, voltage is applied to the piezoelectric element 70 during the expiratory phase, the first valve 54 being therefore open during the expiratory phase only for filling the dosing chamber 56 with additive gas. One extended voltage pulse is applied to the second valve's 58 piezoelectric element 72 during the inspiratory phase, and a corresponding pulse of additive gas is accordingly injected into the main flow of breathing gas.

In this case the dosing chamber 56 should have a somewhat larger volume than the dose to be given. In particular if a gas is to be supplied, since pressure in the dosing chamber will decrease as the dose is given. However, since the pressure difference is large, dosage can still be controlled with high accuracy.

For all examples given above, the system with two valves and an intermittent dosing chamber provides for a safer dosing device. If one valve cease to operate and is jammed in an open position, dosage can still be performed by the other valve. In the alternative the other valve can effectively close the dosing device and prevent further dosing. The extra dosage supplied can in any case never be more than what is contained in the dosage chamber. Combinations of all three examples of control are possible.

FIG. 6 shows a dosing device 88 according to the invention connected to a ventilator/anaesthetic machine 74 for dosing an additive gas or liquid to a breathing gas supplied to a patient 76. The ventilator/anaesthetic machine 74 comprises a system unit 80 (the configuration of which determines whether the system operates as a ventilator, or an anaesthetic machine), an inspiratory tube 82 with a first check valve 84, a patient tube 86 and an expiratory tube 96 with a second check valve 94. The inspiratory tube 82 and the patient tube 86 together form the inspiratory line. The system unit 80 includes gas connections 78A, 78B, 78C for connecting the gas(es) that form the breathing gas and an evacuation connection 98 for evacuating breathing gas from the expiratory tube 96.

When the system unit 80 consists of a ventilator, all gas in the expiratory line 96 is evacuated. When the system unit 80 consists of an anaesthetic machine, more or less of the expired gas can be re-circulated to the patient 76 according to known principles. Neither

the ventilator, nor the anaesthetic machine need therefore be further described here.

The dosing device 88 is in this case connected to the patient tube 86, i. e. as close as possible to the patient 76. The location close to the patient 76 is preferable in many instances since the dosing can be more accurate (the dose of gas or liquid can more reliably reach the target areas in the patient's 76 lungs) when releasing small doses at selected portions of the inspiratory phase. Dosing to the farthest parts of the lungs can in particular be achieved by dosing at, or immediately prior to, onset of the inspiratory phase. Closeness to patient 76 is also advantageous when dosing unstable substances, such as NO.

The dosing device 88 is connected to a supply and control unit 90 for the additive gas or liquid. The gas/liquid is supplied to the dosing device, preferably under high pressure, via supply tube 92. Signal lines 100 connects the dosing device 88 and the supply and control unit 90. In order to obtain accurate concentrations, a meter unit 102 can be arranged in the inspiratory line 82 for measuring inter alia flow and pressure of the breathing gas. Instead of the meter unit 102, or as a complement to this, a signal line 104 between the supply and control unit 90 and the system unit 80 can be used for transferring relevant information between the system unit 80 and the supply and control unit 90. For instance, information regarding flow and pressure of breathing gas generated in the system unit 80 can be transferred to the supply and control unit 90 for control of the dosing device 88.

The supply and control unit 90 can of course be integrated with the system unit 80 in whole or partially. Partial integration can be obtained by integrating all control means into the system unit 80 and have a separate source for the additive gas or liquid connected to the dosing unit 88.

Combinations of the enclosed embodiments can be made where appropriate. In particular can a membrane be used for the first embodiment, as well as no membrane for the second embodiment. The dosing unit 88 can be placed at any location along the inspiration line, even though it is particularly suitable for the advantageous placement in the immediate proximity to the patient. When dosing anaesthetic, the dosing device 88 could even be integrated with the anaesthetic machine. Several dosing units can be connected in series or in parallel, supplying the same or different additive gases or liquids.

## Claims

1. A dosing device (86) for adding small amounts of an additive gas or liquid to a breathing gas, intended to be supplied to a subject (76) via an inspiratory line (82, 86) in an anaesthetic machine (74) or ventilator during inspiratory phases, characterized in that the dosing device (86) is adapted to be connected to the inspiratory line (82, 86) in proximity to the

- subject, the dosing device (86) comprises a constant-volume dosing chamber (6; 56), the volume of which is up to a magnitude essentially equal to the dosage to be added during one inspiratory phase, an inlet (2; 55) with a first valve (4; 54), adapted for connection to a source (90) of gas or liquid supplying an additive gas or liquid at a predetermined, constant, positive pressure, an outlet (10) with a second valve (8; 58) for carrying a gas or liquid from the dosing chamber (6; 56) to the breathing gas, operating means (20, 22; 70, 72) for controlled opening and closing of the valves (4, 8; 54, 58) and a control unit (90), arranged to cause the operating means (20, 22; 70, 72) to at least open the second valve (8; 58) for one or a plurality of predetermined intervals during the inspiratory phase.
2. The dosing device according to claim 1, **characterized** in that the control unit (90) is arranged to cause the operating means (20, 22; 70, 72) to open the first valve (4; 54) for filling the dosing chamber (6; 56) with additive gas or liquid under positive pressure, close the first valve (4; 54) and then open the second valve (8; 58).
  3. The dosing device according to claim 2, **characterized** in that the control unit (90) is arranged to cause the operating means (20, 22; 70, 72) to sequentially open and close the first valve (4; 54) and the second valve (8; 58) during the inspiratory phase.
  4. The dosing device according to claim 2, **characterized** in that the control unit (90) is arranged to cause the operating means (20, 22; 70, 72) to open the first valve (4; 54) for filling the dosing chamber (6; 56) with additive gas or liquid during the expiratory phase.
  5. The dosing device according to claim 1, **characterized** in that the control unit (90) is arranged to cause the operating means (20, 22; 70, 72) to open the first valve (4; 54) for filling the dosing chamber (6; 56) with additive gas or liquid and simultaneously open the second valve (8; 58) for dosing the additive gas or liquid.
  6. The dosing device according to any of the above claims, **characterized** in that the operating means (20, 22) consist of piezoelectric elements which, when activated, are arranged to lift a valve body (24, 26) off its valve seat (36, 38), thereby opening the valve (4, 8).
  7. The dosing device according to any of the above claims, **characterized** in that the first valve (4) is devised so positive pressure from a connected source (90) of gas or liquid causes the valve body (24) to move in the closing direction.
  8. The dosing device according to any of the above claims, **characterized** in that the dosing device is made of micromachined silicon.
  9. The dosing device according to claim 8, **characterized** in that the inlet (2), the first valve (4), the dosing chamber (6), the second valve (8) and the outlet (10) are laterally arranged in micromachined and bonded discs (12, 14, 16, 18) made of silicon and, possibly, glass.
  10. The dosing device according to claim 8, **characterized** in that the inlet (55), the first valve (54), the dosing chamber (56), the second valve (58) and the outlet, are arranged in a stack.

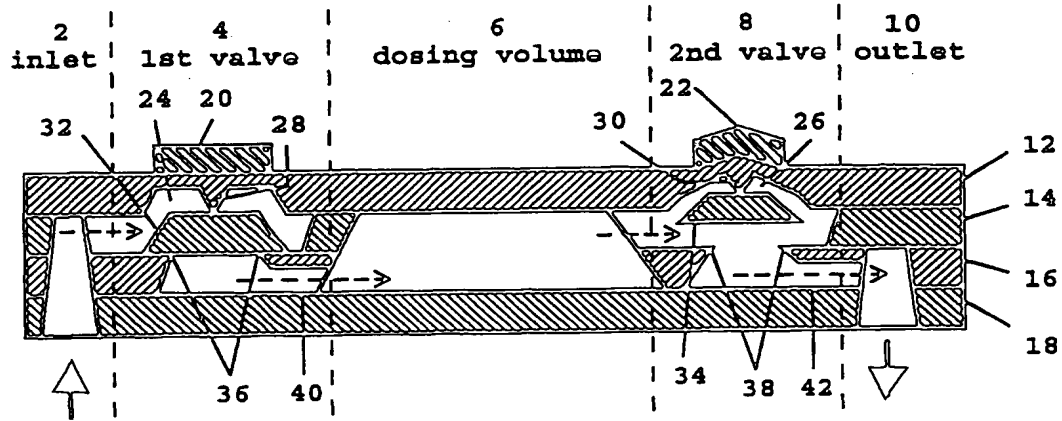


FIG. 1

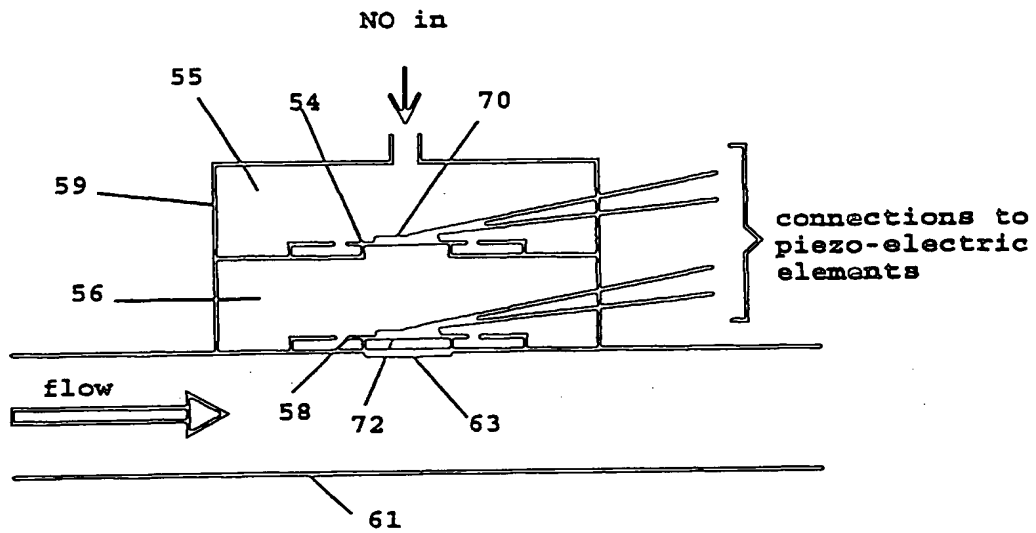


FIG. 2

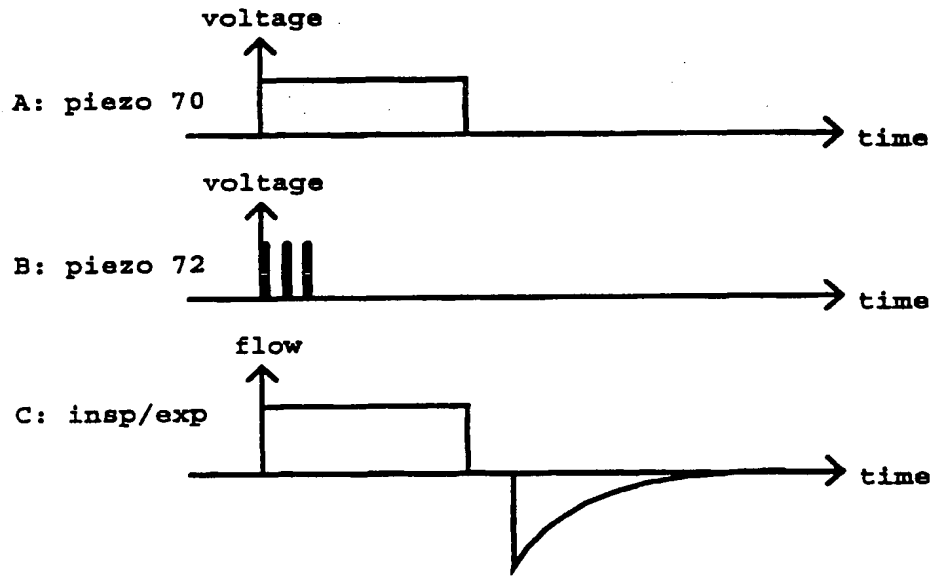


FIG. 3

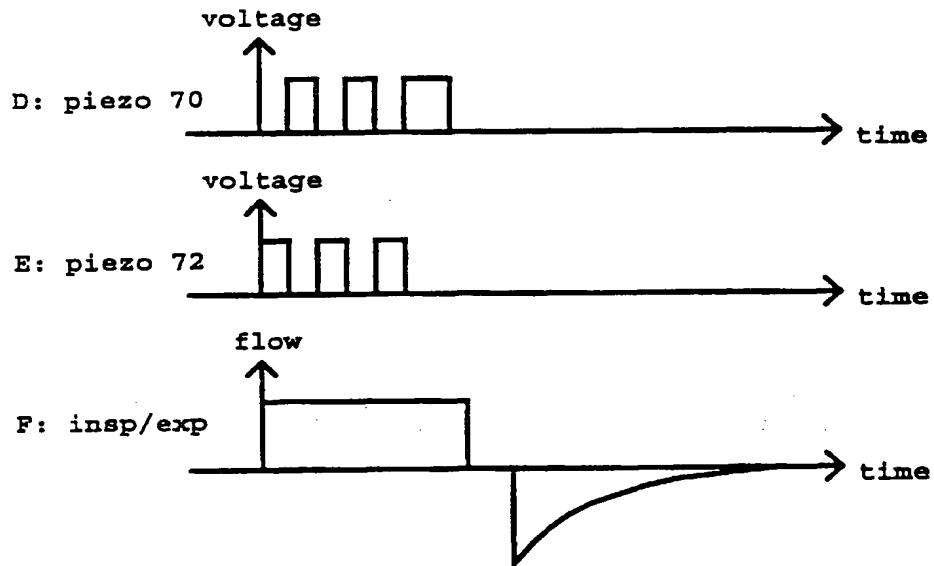


FIG. 4



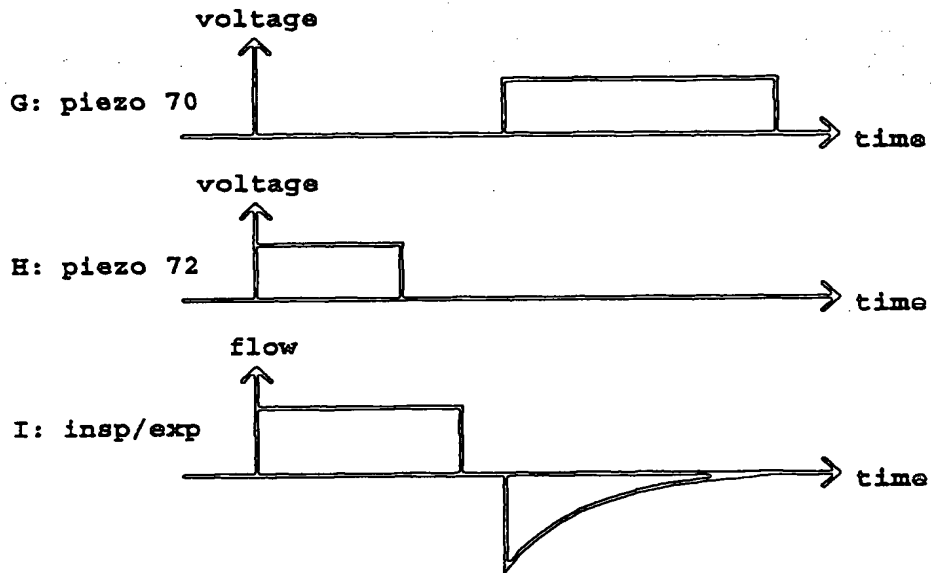


FIG. 5

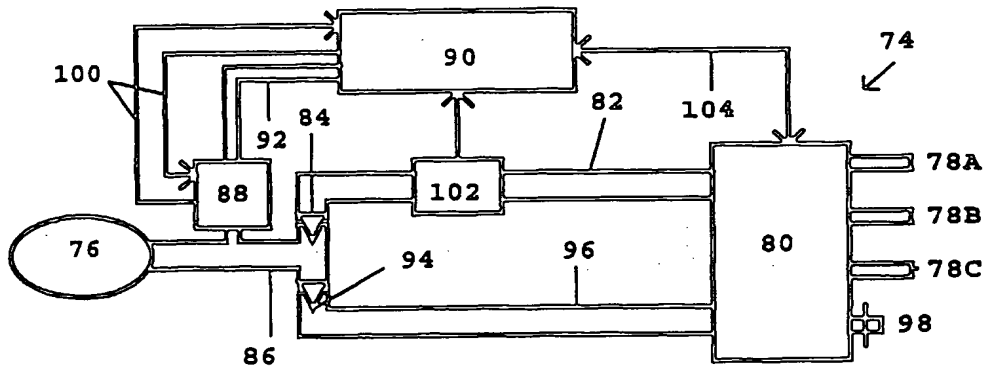


FIG. 6



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## EUROPEAN SEARCH REPORT

Application Number  
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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	GB 2253353 A (DRÄGERWERK AKTIENGESELLSCHAFT (INCORPORATED IN THE FEDERAL REPUBLIC OF GERMANY)), 9 September 1992 (09.09.92) * page 6, line 28 - page 10, line 9 *	1-10	A61M 16/10
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A	Patent Abstracts of Japan, Vol 11, No 215, M-606, abstract of JP, A, 62-31784 (HITACHI METALS LTD), 10 February 1987 (10.02.87) * abstract, figure *	6	
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A	US 4895500 A (BERTIL HÖK ET AL.), 23 January 1990 (23.01.90) * abstract and figures *	8-10	
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			TECHNICAL FIELDS SEARCHED (Int. Cl.6)
			A61M F16K
The present search report has been drawn up for all claims			
Place of search STOCKHOLM		Date of completion of the search 1 July 1997	Examiner TOMMY SOMLO
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